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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,546	12/05/2003	Charles C. Rancy	7404-541	1896

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WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP
111 MONUMENT CIRCLE, SUITE 3700
INDIANAPOLIS, IN 46204-5137

EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT	PAPER NUMBER
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3736

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/729,546	Applicant(s) RANEY ET AL.	
	Examiner Jeffrey G. Hoekstra	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 14-18, 21-23 and 31-47 is/are pending in the application.
- 4a) Of the above claim(s) 31-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 14-18 and 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

1. In response to the amendments filed on 10/16/2006 and 01/16/2007, amended claim(s) 1, 7, 14, and 18, canceled claim(s) 11-13, 19-20, and 24-30, new claim(s) 31-47, and withdrawn claim(s) 31, 35-36, and 42-47 is/are acknowledged. The current rejections of the claim(s) 1-10, 14-18, and 21-23 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Election/Restrictions

2. Applicant's election with traverse of Group I, drawn to claims 1-10, 14-18, 21-23, and 31-42, and Species D, embodiment drawn to Figures 11-12, in the reply filed on 01/16/2007 is acknowledged. The traversal is on the ground(s) that the claims could be examined together without serious burden. This is not found persuasive because the inventions as disclosed are structurally divergent and distinct subject matter and the apparatus as broadly as structurally claimed the apparatus may be used to practice another and materially different process including at least phlebotomies for bloodletting.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 31-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 01/16/2007. The Examiner notes claims 33, 34, and 37-41 are drawn to a nonelected Species comprising a sampling system having a lancing device.

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4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. This application contains claims 31-47 drawn to an invention nonelected with traverse in Paper No. 20070116. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Objections

6. Claims 6 and 16 are objected to because of the following informalities: the term "about" is a relative term that appears to render the claim(s) indefinite. The term "about" is not defined by the claim(s), the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The magnitude of the obtuse angle is unclear. Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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8. Claims 1-10, 14-18, and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Abbott Laboratories (WO 98/24366) as broadly as *structurally* claimed.

9. Regarding claims 1, 4, 7, 8, 14, 18, and 23, Abbott Laboratories discloses a test strip (1000, 1200, 3000), comprising:

- a body (1002, 3001) having a first end (the left side as best seen in Figures 32 and 46A), a second end (the right side as best seen in Figures 32 and 46A), a top surface (the top as best seen in Figures 32 and 46A), a bottom surface (the bottom as best seen in Figures 32 and 46A),
- said body defining a sampling passageway (the volume of space defined by element 1010 and 3010 as best seen in Figures 32 and 46A) including an inlet opening (1012, 3007 as best seen in Figures 32 and 46A, and pages 63-64) communicating with an end edge (3012) at a location spaced from the bottom surface, and said body defines a recessed surface (3008) extending between said inlet opening and said bottom surface (pages 29-30); and
- a sealing member (1010, 3002) on said bottom surface that extends from a first side edge to a second side edge (the edges defined by said recessed surface walls 3008, pages 63-64) and is positioned to contact and seal with the skin when said body is pressed against the skin (pages 63-64).

10. Regarding claims 2, 3, 9, 10, and 21, Abbott Laboratories discloses a deformable, hydrophobic seal (pages 28 and 64).

11. Regarding claims 5, 6, 15, and 16, Abbott Laboratories discloses the recessed surface as extending at an obtuse angle from the bottom surface to the inlet opening (as

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best seen in Figure 32) and shows said angle ranging from about 100 to about 150 degrees.

12. Regarding claim 17, Abbott Laboratories discloses the inlet opening spaced from said top surface (as best seen in Figures 32 and 46A).

13. Regarding claim 22, Abbott Laboratories discloses the sealing member on the bottom surface aligned with the inlet opening and positioned to contact and seal with the skin when said body is pressed against the skin (pages 63-64).

Response to Arguments

14. Applicant's arguments with respect to claims 1-10, 14-18, and 21-23 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571) 272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JH

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Max F. Hindenburg
MAX F. HINDENBURG
SUPERVISOR
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